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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,173	10/01/2003	Michael Hugh Quinn	CL/V-32421	6787

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

HUANG, MEI QI

ART UNIT	PAPER NUMBER
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1713

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/676,173

Applicant(s)

QUINN ET AL.

Examiner

Mei Q. Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 7-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office Action is in response to the Amendment mailed on June 6, 2005. Claims 1 and 8 have been amended, claims 5-6 and 10-15 have been withdrawn from further consideration due to restriction action, claims 16-46 are cancelled. Claims 1-4 and 7-9 are now pending.
2. The objection to the claim 8 has been obviated by appropriate claim amendment.
3. The prior art rejection of claims 1-4 and 7-9 under 35 U.S.C. 102(b) as being anticipated by Müller (US Pat. 6,303,687) is maintained. The response to applicant's arguments is detailed below.

Specification

4. The disclosure is objected to because of the following informalities: On page 11, line 10, "the hydrophilic groups or units the copolymer" should be changed to "the hydrophilic groups or units of the copolymer". Appropriate correction is required.

Claim Objections

5. Claim 1-4 and 7-9 are objected to because of the following informalities: The phrase in claim 1, line 11-13, is suggested that the phrase be amended to recite "a modifier which is materially different from but miscible with water-soluble polyvinyl alcohol and presented in the polymerizable material in an amount ...". Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 1-4 and 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "materially different" in claim 1 renders the claim indefinite because the requisite degree of difference is unclear. The phrase "materially different" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Müller (US Pat. 6,303,687).

The basis of the rejection and the examiner's position regarding the applied prior art are adequately set forth in the previous Office Action dated April 26, 2005 and incorporated herein by reference.

Response to Arguments

10. Applicant's arguments filed on June 6, 2005 have been fully considered but they are not persuasive.

Applicant argues that The modifier units taught by Müller is integral parts of a water-soluble polyvinyl alcohol and the modifier, according to the present application, is not integral parts of a water-soluble polyvinyl alcohol. Applicant is advised that the instantly indicated modifier not being an integral part is not defined either by claim or specification. In contrast, the disclosure on the instant specification, page 11, lines 8-14, indicates that the hydrophilic groups or units of the copolymer are intertwined with the polymer meshwork of polyvinyl alcohol.

Applicant also argues that Müller does not suggest anything about a modifier which is selected from the group consisting of nanoparticles having a hydrophilic surface (examiner's note: a non-elected species) and a copolymer having a balanced composition of hydrophilic and hydrophobic groups or units (the instant specification, page 11, lines 27-28). However, Müller teaches the use of a hydrophobic vinylic comonomer or a mixture of a hydrophobic vinylic comonomer and a hydrophilic vinylic comonomer which comprises at least 50 percent by weight of a hydrophobic vinylic comonomer to improve the mechanical properties of the crosslinked polymer which can be used to make contact lenses, such as freedom from stresses and tear strength (column 14, lines 10-16, and column 15, lines 43-44). Furthermore, Müller discloses that vinyl acetate is a preferred hydrophobic vinylic comonomer and N-vinylpyrrolidone is a preferred hydrophilic vinylic comonomer (column 15, lines 9-12). Müller's teaching

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of the comonomers which are the monomer components of a copolymer having a balanced composition of hydrophilic and hydrophobic groups or units is seen to anticipate the copolymer having a balanced composition of hydrophilic and hydrophobic groups or units as instantly claimed.

In regarding the limitation of modifier being able to improve one or more physical properties of the ophthalmic device, given the similarity in the polymerizable material composition between the prior art and the present application, it is the examiner's position to believe that the prior art composition must inherently possess the same improved physical properties. Since the PTO does not have proper means to conduct experiments, the burden of proof is now shifted to the applicant to establish an unobviousness difference. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596, (CCPA 1980).

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mei Q. Huang whose telephone number is (571) 272-3549. The examiner can normally be reached on 8am - 4pm, Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mei Q. Huang
Examiner

July 26, 2005



FRED TESKIN
PRIMARY EXAMINER
1213